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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,043	02/13/2004	Eliezer Rapaport	21095-00008-US1	3919

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EXAMINER	
ANDERSON, JAMES D	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,043	RAPAPORT, ELIEZER	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 11/2/2006, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application. In light of the new rejections being applied against the pending claims this Office Action is Non-Final.

Status of the Claims

Claims 1-2 and 4-12 are currently pending and are the subject of this Office Action.

Claim Rejections - 35 USC § 112 (1st Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 and 4-12 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an Enablement rejection.

To be enabling, the specification of the patent application must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1561 (Fd. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[1]

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence or absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

[1] As pointed out by the court in *In re Angstadt*, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not "experimentation".

7) the predictability of the art, and

8) The breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill of those in the art

The invention relates to a method of obtaining weight loss in a human comprising administering caffeine or theophylline and adenosine, adenosine 5'-monophosphate (AMP) or adenosine 5'-triphosphate (ATP). Applicant's invention is based on the theory that chronic administration of adenosine, AMP or ATP will lead to desensitization of adenosine receptors, thereby leading to increased lipolysis. It is further asserted that this desensitization of adenosine receptors will also lead to increased antagonism of the adenosine receptors by caffeine or theophylline, resulting in further lipolysis (col. 4, lines 47-67). The relative skill of those in the art is high, generally that of an M.D. or Ph.D. That factor is outweighed, however, by the unpredictable nature of the art. As illustrative of the state of the art, the examiner cites Rapaport *et al.* (Biochemical Pharmacology, 1989, vol. 38, pages 4261-4266) (of record) and Applicant's disclosure.

Rapaport *et al.*, cited for evidentiary purposes, teaches that *i.p.* injections of AMP and ATP resulted in an inhibition of host weight loss in tumor-bearing mice (Abstract). AMP or ATP were administered daily (*i.e.* chronic) (page 4262). If chronic AMP or ATP administration desensitized adenosine receptors as asserted in the instant disclosure, one would have expected the mice to lose weight due to increased lipolysis. Further, Applicant discloses at column 7, line 66 to column 8, line 6 of the instant specification that administration of adenosine or any of its pro-drugs by injection or infusion results in acutely elevated levels of adenosine. However, the instantly claimed methods require chronically elevated levels of adenosine in order to desensitize adenosine receptors. Further still, adenosine only has a blood plasma half-life of 3-6 seconds (column 3, lines 55-56). Thus, it is not apparent how administration of AMP, ATP or adenosine "per 24 hours" as instantly claimed will result in the increased plasma levels of adenosine necessary to desensitize adenosine receptors. While chronic administration of synthetic A_1 adenosine receptor agonists were reported to produce desensitization of heart adenosine A_1 receptors, no such desensitization has been demonstrated with AMP, ATP or adenosine administration.

The art of obtaining weight loss by administering, for example, a pill, is unpredictable, particularly in the case of AMP, ATP or adenosine being used to illicit weight loss by desensitizing adenosine receptors.

2. The breadth of the claims

The claims are reasonably narrow, reciting methods of inducing weight loss by administering caffeine (or theophylline) and AMP, ATP or adenosine. However, in their

broadest reasonable interpretation, the claims read on a person eating carbohydrates, proteins or fats and consuming caffeine (*e.g.* a Coke or cup of coffee). Carbohydrates, proteins and fats all contribute to muscle energy systems and therefore all contribute to ATP levels in the body.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides reasonably specific guidance with respect to the administration of an enteric-coated ATP tablet. However, with respect to administering AMP or adenosine there is no guidance. Further, Applicant states that injection or infusion of adenosine or its prodrugs leads to acutely elevated levels of adenosine, not chronically elevated levels.

While the specification has two examples wherein ATP tablets are administered to volunteers and weight loss monitored, these experiments are not scientifically controlled. Further, when one compares Example 3 (no caffeine) to Example 4 (with caffeine), it is clear that caffeine consumption had no effect on weight loss. However, it is well established in the art that caffeine is an antagonist of adenosine receptors and therefore induces lipolysis. As such, one would expect more weight loss in volunteers consuming caffeine while taking ATP if, in fact, ATP desensitized adenosine receptors as asserted in the specification. This, however, was not the case. The patients in both groups (a total of four people) lost the same amount of weight, whether caffeine was consumed or not. Further, it is not clear if (and if so, how) the diet and exercise of the volunteers was monitored and controlled. As such, it is simply not scientifically reasonable to conclude that the weight loss of the volunteers was due to ATP or ATP/caffeine consumption.

Finally, there is no reasonable expectation that administration of adenosine, ATP or AMP will lead to desensitization of adenosine receptors. There are no experimental methods described that would allow the skilled artisan to actually scientifically test whether adenosine receptors can be desensitized by exogenous administration of adenosine, ATP or AMP.

4. The quantity of experimentation necessary

Because of the known unpredictability of the art (as discussed *supra*) and in the absence of experimental evidence commensurate in scope with the claims, the skilled artisan would not accept the assertion that administration of adenosine, ATP or AMP and caffeine or theophylline will lead to weight loss as inferred in the claims and contemplated by the specification. In fact, the experiments provided in the specification do not support this assertion without more controlled experiments. The weight loss (4-5 pounds) experienced by the volunteers cannot be attributed to ATP and caffeine consumption without knowing when the patients were weighed (day vs. night), their exercise regimen and their diet. Further, there is no control group that did not take ATP.

Accordingly, the instant claims do not comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, since to practice the claimed invention a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson, Ph.D.
Patent Examiner
AU 1614

March 16, 2007

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER

3/16/07